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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. ONORATO & CO., INC., a corporation, DAVID L. PIROTTO and JOSEPH V.H. D'AMATO, individuals, Defendants.	Case No. _____ **COMPLAINT FOR PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This action is brought by the United States of America under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain Onorato & Company, Inc. ("Onorato"), a corporation, David L. Pirotto and Joseph V.H. D'Amato, individuals (collectively, "Defendants"), from violating 21 U.S.C. § 331(k), by causing food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such food is held for sale after shipment of one or more of its components in interstate commerce.

//

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332(a), and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

INTRADISTRICT ASSIGNMENT

4. The conduct at issue in this action took place in substantial part in San Mateo County.

DEFENDANTS

5. Onorato is a California corporation located at 390 Swift Avenue, Ste. 17, South San Francisco, CA 94080, within the jurisdiction of this Court.

6. Defendant David L. Pirotto is the Owner and President of Onorato. He is the most responsible person at the company. Defendant Pirotto's duties include managing Onorato's daily operations, including ordering, receiving, processing, packing, marketing, and distribution. He is responsible for hiring and firing employees, financial decisions, and initiating and implementing corrective actions. He performs his duties at 390 Swift Avenue, Ste. 17, South San Francisco, CA 94080, within the jurisdiction of this Court.

7. Defendant Joseph V.H. D'Amato is the General Manager of Onorato. Along with Defendant Pirotto, Defendant D'Amato is responsible for ordering and receiving food, maintaining all Hazard Analysis Critical Control Point ("HACCP") records, and distributing finished products to customers. Although Defendant Pirotto has the power to initiate and implement corrective actions for seafood HACCP violations, Defendant D'Amato shares responsibility for the company's operations and seafood HACCP plans. At the close of each inspection of Defendants' facility since May 2012, the FDA investigators discussed their inspectional observations with Defendants Pirotto and D'Amato. Defendant D'Amato performs his duties at 390 Swift Avenue, Ste. 17, South San Francisco, CA 94080, within the jurisdiction of this Court.

8. Onorato receives, processes, packs, holds, and distributes a variety of fish and fishery products, including ready-to-eat raw tuna, unpasteurized and pasteurized crabmeat, and pre-packaged smoked and non-smoked histamine-forming species of fish. Its products are received, processed, packed, held, and distributed at and from the company's facility located at 390 Swift Avenue, Ste. 17,

South San Francisco, California 94080, within the jurisdiction of this Court.

9. Defendants receive fish and fishery products from California distributors who import the products from foreign suppliers, and distribute their finished products to customers within California.

FOOD SAFETY

10. *Clostridium botulinum* ("*C. bot.*") is an anaerobic bacterium, meaning that it thrives in oxygen-free environments. All people are susceptible to *C. bot.*'s neurotoxin that *C. bot.* spores can produce in food. Ingesting even a small amount of this neurotoxin can cause botulism. Although the incidence of botulism is rare, the disease can cause paralysis and has a high mortality rate if it is not treated promptly.

11. *C. bot*. is a pathogen that is widely distributed in nature and may be found in any raw fish or fishery product. Because its spores are heat-resistant, *C. bot*. can survive cooking. *C. bot.* can also survive in food that has been incorrectly or minimally processed. Certain strains of *C. bot.*, called proteolytic strains, produce offensive odors and tastes in food products, and can grow at temperatures as low as 50°F. In contrast, non-proteolytic strains of *C. bot.* do not produce the same sensory signals. These non-proteolytic strains are particularly dangerous because they can grow and produce toxin at refrigeration temperatures (as low as 38°F), rendering a food toxic without any signs of spoilage. Toxin formation by non-proteolytic *C. bot.* can occur at temperatures above 38°F. In foods that rely on refrigeration to inhibit the growth of *C. bot*., seafood processors must employ appropriately rapid cooling processes after cooking to prevent pathogen growth and toxin formation.

12. *Listeria monocytogenes* ("*L. mono*") is the bacterium that causes listeriosis, a disease commonly contracted by eating food contaminated with *L. mono*. Listeriosis can be serious, even fatal, for vulnerable groups such as newborns and those with impaired immune systems. The most serious forms of listeriosis can result in meningitis and septicemia. Pregnant women may contract flu-like symptoms from listeriosis, and complications from the disease can result in miscarriage or septicemia in the newborn.

13. Unlike many other foodborne microbes, *L. mono* can adapt and grow at refrigeration temperatures or under other adverse conditions, such as high-salt or high-acid (low pH) conditions. The presence of *L. mono* in a facility processing ready-to-eat foods presents a particularly significant public

health risk.

14. To minimize the potential for *L. mono* contamination, it is necessary to have sanitation procedures that prevent contamination of food contact surfaces and to eliminate niches where *L. mono* can become established, grow, and persist. Strict in-plant sanitation measures must be taken to eliminate *L. mono* and prevent its proliferation.

15. The Act and its implementing regulations require a seafood processor to control the risk of *C. bot.* and *L. mono* formation if the bacteria are reasonably likely to grow in the processor's seafood products. *See* 21 U.S.C. § 342(a)(4); 21 C.F.R. §§ 123.6(a)-(c).

16. Processing histamine-forming species (e.g., tuna, mahi-mahi, escolar, yellowtail, and wahoo) without developing and implementing an adequate HACCP program can lead to histamine formation in fish. Some species of fish are susceptible to the formation of histamine when time and temperature conditions allow for the growth of spoilage bacteria. Accumulation of histamine and some other spoilage by-products in the flesh of the fish is collectively known as scombrotoxin. Fish and fishery product processors can minimize the growth of spoilage organisms and the formation of scombrotoxin by preventing exposure to potentially unsafe times and temperatures by, among other things, limiting the amount of time scombrotoxin-forming fish are exposed to temperatures above 40°F during receiving, storing, and processing.

17. Consuming fish containing scombrotoxin can result in an illness known as scombrotoxin poisoning, histamine poisoning, or scombroid poisoning. This illness can cause rash, hives, nausea, dizziness, vomiting, and diarrhea of varying degrees of severity and may require hospitalization, particularly in the case of elderly, very young, or immune-impaired persons. In severe cases, an asthmatic-like constriction of the air passage, heart palpitations, and respiratory stress have been reported.

18. Several foods contain allergenic proteins that are naturally part of the food. These allergens pose a health risk to certain sensitive individuals who are allergic to these proteins. The symptoms of food allergies can include tingling of the mouth, swelling of the tongue and throat, difficulty breathing, hives, vomiting, abdominal cramps, diarrhea, drop in blood pressure, loss of consciousness, and in severe cases, death.

19. All foods that are not raw agricultural commodities and that contain a major food allergen must be labeled to clearly identify the name of the food source from which the allergen is derived. *See* 21 U.S.C. § 343(w)(1). "Major food allergen" means any of the following: milk, eggs, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts, wheat, peanuts, and soy beans. 21 U.S.C. § 321(qq)(1).

20. An adequate HACCP plan to control the hazard of undeclared allergens includes controls to ensure that the correct name is listed on the product labeling.

REGULATORY FRAMEWORK

21. Defendants' fish and fishery products are "food" within the meaning of the Act. *See* 21 U.S.C. § 321(f).

22. Food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

23. A seafood processor's failure to comply with the requirements of the seafood HACCP regulations, 21 C.F.R. Part 123, renders its fish or fishery products adulterated under the Act. *See* 21 U.S.C. § 342(a)(4); 21 C.F.R. §§ 123.6(g), 123.12(d).

24. The seafood HACCP regulations require every fish and fishery product processor to "conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur" during the processing of each kind of its fish or fishery products. 21 C.F.R. § 123.6(a). A food safety hazard is "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." 21 C.F.R. § 123.3(f).

25. Whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur during processing, the processor must develop and implement an adequate HACCP plan to control the identified food safety hazards. 21 C.F.R. § 123.6(b). Among other things, a HACCP plan must:

A. Identify critical control points ("CCPs"), which are points, steps, or procedures in a food manufacturing process at which controls can be applied to prevent, eliminate, or reduce a food safety hazard to an acceptable level. *See* 21 C.F.R. §§ 123.3(b) and 123.6(c)(2); and

B. Identify critical limits at each CCP, which are the maximum or minimum values within which a physical, biological or chemical parameter must be maintained to prevent, eliminate, or reduce to an acceptable level, the occurrence of the identified food safety hazard(s). *See* 21 C.F.R. §§ 123.3(c) and 123.6(c)(3).

26. A seafood processor must also:

A. Take corrective action whenever a deviation from a critical limit occurs. 21 C.F.R. § 123.7;

B. Verify that its HACCP plan is adequate to control food safety hazards reasonably likely to occur and that the plan is being effectively implemented. 21 C.F.R. § 123.8(a);

C. Record its sanitation activities, 21 C.F.R. § 123.11(c), and maintain additional appropriate records, such as documentation of CCPs, corrective actions taken, and HACCP plan verification activities. 21 C.F.R. §§ 123.6-123.9; and

D. Monitor, with sufficient frequency, sanitation controls and practices used during processing to ensure that they conform with the current Good Manufacturing Practice ("cGMP") requirements for food including, but not limited to, prevention of cross-contamination from insanitary objects. 21 C.F.R. § 123.11(b) (*see also* 21 C.F.R. §§ 110.35(a) and (d)(2)).

27. Defendants are subject to the seafood HACCP regulations because they engage in the "processing," within the meaning of 21 C.F.R. § 123.3(k)(1), of "fish" or "fishery product," within the meaning of 21 C.F.R. §§ 123.3(d) and (e).

28. Food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) if it is prepared, packed, or held in a facility that does not comply with cGMP requirements for food, 21 C.F.R. Part 110. *See* 21 C.F.R. § 110.5(a).

DEFENDANTS' VIOLATIONS

29. Defendants violate 21 U.S.C. § 331(k) by causing food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such food is held for sale after shipment of one or more components in interstate commerce.

30. Defendants' food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated

with filth or may have been rendered injurious to health. Such insanitary conditions include:

A. Defendant's failure to implement effective sanitation controls in accordance with food cGMP requirements, 21 C.F.R. Part 110; and

B. Defendants' failure to comply with the seafood HACCP regulations, 21 C.F.R. Part 123, by, among other deficiencies, failing to adequately control the risk of *C. bot.* and *L. mono* growth and toxin formation in susceptible fish and fishery products and failing to sufficiently monitor sanitation conditions and practices during processing.

HISTORY OF VIOLATIONS

31. The Food and Drug Administration ("FDA") inspected Onorato's facility nine times: December 2017, November 2016, September 2015, February 2013, May 2012, August 2011, November 2008, May 2007, and June 2006. During each inspection, FDA investigators found the same or similar types of insanitary conditions, as well as repeated violations of the Act and the cGMP and seafood HACCP regulations.

December 2017 Inspection

32. During FDA's inspection of Defendants' facility between December 12 and 18, 2017 (the "December 2017 inspection"), FDA investigators documented significant cGMP and seafood HACCP deficiencies. At the close of the inspection, FDA investigators issued a List of Inspectional Observations ("Form FDA-483") to Defendant Pirotto that included, but was not limited to, the following observations:

<u>cGMP Violations</u>

A. Failure to clean and sanitize food-contact surfaces when the food-contact surfaces may have become contaminated, in violation of 21 C.F.R. § 110.35(d)(2);

B. Failure to ensure that all persons working in direct contact with food, food-contact surfaces, and food-packaging materials conform to hygienic practices to protect against food contamination, in violation of 21 C.F.R. § 110.10(b)(1);

<u>Seafood HACCP Violations</u>

C. Failure to list in the HACCP plan the food safety hazards that are reasonably likely to occur, in violation of 21 C.F.R. § 123.6(c)(1);

D. Failure to implement the monitoring, recordkeeping, and verification procedures listed in the HACCP plan, in violation of 21 C.F.R. § 123.6(b);

E. Failure to include in the HACCP plan a corrective action plan to ensure affected product is not entered into commerce and the cause of the deviation is corrected, in violation of 21 C.F.R. § 123.7(b);

F. Failure to maintain sanitation control records that accurately document the observed conditions or practices, in violation of 21 C.F.R. § 123.11(c); and

G. Failure to list in the HACCP plan monitoring procedures and frequencies that ensure compliance with the critical limit, in violation of 21 C.F.R. § 123.6(c)(4).

33. During the December 2017 inspection, FDA investigators collected fifty environmental sub-samples from the fish-processing room and cooler. Nine tested positive for *L. mono*, including samples taken from the plastic curtain between the staging area and the fish-processing room, the table holding the fish weight scale, the surface of the fish weight scale, the floor mat under the west wall processing table, and the drain under the west processing table.

Prior Inspections

34. FDA inspected Defendants' facility between October 31 and November 9, 2016 (the "November 2016 inspection"). At the close of the November 2016 inspection, FDA investigators issued Defendant Pirotto a Form FDA-483 that included, but was not limited to, the following observations:

cGMP Violations

A. Defendants' employee: (a) spraying the *L. mono*-contaminated scale and a processing table in the same water stream, and failing to re-clean and sanitize the processing table; and (b) cleaning the rubber floor mat contaminated with *L. mono* with a high-pressure hose, causing the water stream to strike previously cleaned cutting boards (i.e., direct food-contact surfaces) that were not re-cleaned and sanitized, in violation of 21 C.F.R. § 110.35(a);

B. Failure to use sanitizer as necessary to protect against cross-contamination from the floor to food-contact surfaces, in violation of 21 C.F.R. § 110.35(d)(2);

Seafood HACCP Violations

C. Failure to prevent cross-contamination from an insanitary object to food-contact

surfaces, in violation of 21 C.F.R. § 123.11(b)(3);

D. Failure to list in the HACCP plan food safety hazards that are reasonably likely to occur, in violation of 21 C.F.R. § 123.6(c)(1);

E. Failure to include in the HACCP plan a corrective action plan to ensure affected product is not entered into commerce and the cause of the deviation is corrected, in violation of 21 C.F.R. § 123.7(b); and

F. Failure to maintain sanitation control records that document actual conditions, in violation of 21 C.F.R. § 123.11(c).

35. During the November 2016 inspection, FDA investigators collected fifty environmental sub-samples from Defendants' fish-processing room. Three tested positive for *L. mono*, including a rubber floor mat and the surface of the fish weight scale, where *L. mono* was detected during the December 2017 inspection. In addition, five of the sub-samples tested positive for *Listeria innocua* ("*L. innocua*"), a non-pathogenic a bacterium whose presence in a food-processing facility is an indicator of insanitary conditions.

36. Between 2006 and 2015, FDA inspected Defendants' facility seven times. During each inspection, FDA investigators observed the same or similar significant violations of the Act and the cGMP and seafood HACCP regulations as those observed during prior inspections. At the close of each inspection, FDA investigators issued a Form FDA-483 to Defendant Pirotto and discussed with him and, since the May 2012 inspection, also with Defendant D'Amato, the serious cGMP and seafood HACCP violations observed.

History

37. Defendants have been repeatedly warned that their operations violate the law and that their failure to implement corrective actions could lead to regulatory action. At the close of each inspection between 2006 and 2017, FDA investigators presented Defendant Pirotto with a Form FDA-483 and discussed with him their observations of objectionable conditions and practices at Defendants' facility. At the close of the May 2012 inspection and for each inspection thereafter, these discussions included Defendant D'Amato.

38. The individual Defendants attended telephonic regulatory meetings with FDA on June

20, 2017, and August 1, 2012. During each meeting, FDA representatives discussed Defendants' previous violations and their repeated failures to correct these violations.

39. FDA issued the company and Defendant Pirotto a Warning Letter, dated October 25, 2011, notifying them that they were in violation of the cGMP and seafood HACCP regulations, causing their products to be adulterated under the Act. The Warning Letter cautioned Defendants that if they failed to promptly correct their violations, FDA may pursue further regulatory action, including an injunction.

40. Defendants have repeatedly promised to take corrective actions and comply with the Act's statutory and regulatory requirements. However, as evidenced by the repeated violations observed during FDA's December 2017 inspection, Defendants have failed to take effective measures to bring their seafood-processing operations into compliance with the law.

The United States believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. § 331(k).

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships), cease receiving, preparing, processing, packing, holding, or distributing articles of food, at or from the Onorato facility or at any other current or future location, unless and until Defendants bring their receiving, preparing, processing, packing, holding, and food distribution into compliance with the Act and applicable regulations, to FDA's satisfaction;

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships), from directly or indirectly violating 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4);

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s)

of business and all records relating to the receiving, preparing, processing, packing, holding, and distribution of food to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Order that Plaintiff be awarded costs incurred in pursuing this action, including the costs of investigation to date, and such other equitable relief as the Court deems just and proper.

DATED this 27th day of November, 2018.

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General
Civil Division

ALEX G. TSE
United States Attorney

JAMES M. BURNHAM
Deputy Assistant Attorney General

GUSTAV W. EYLER
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CIVIL COVER SHEET

The JS-CAND 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
United States of America

(b) County of Residence of First Listed Plaintiff *(EXCEPT IN U.S. PLAINTIFF CASES)*

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
James T. Nelson, U.S. Department of Justice, 450 Fifth Street, N.W., Room 6400-South, Washington, DC 20001, 202-616-2376

DEFENDANTS
Onorato & Co., Inc., Pirotto, David L., and D'Amato, Joseph V.H.

County of Residence of First Listed Defendant *(IN U.S. PLAINTIFF CASES ONLY)* San Mateo County

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*
Christopher Van Gundy, Keller and Heckman LLP, Three Embarcadero Center, Suite 1420, San Francisco, CA 94111, 415-948-2831

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- [X] 1 U.S. Government Plaintiff
- [ ] 2 U.S. Government Defendant
- [ ] 3 Federal Question *(U.S. Government Not a Party)*
- [ ] 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(For Diversity Cases Only)* *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

	PTF	DEF		PTF	DEF
Citizen of This State	[ ] 1	[ ] 1	Incorporated *or* Principal Place of Business In This State	[ ] 4	[ ] 4
Citizen of Another State	[ ] 2	[ ] 2	Incorporated *and* Principal Place of Business In Another State	[ ] 5	[ ] 5
Citizen or Subject of a Foreign Country	[ ] 3	[ ] 3	Foreign Nation	[ ] 6	[ ] 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- [ ] 110 Insurance
- [ ] 120 Marine
- [ ] 130 Miller Act
- [ ] 140 Negotiable Instrument
- [ ] 150 Recovery of Overpayment Of Veteran's Benefits
- [ ] 151 Medicare Act
- [ ] 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- [ ] 153 Recovery of Overpayment of Veteran's Benefits
- [ ] 160 Stockholders' Suits
- [ ] 190 Other Contract
- [ ] 195 Contract Product Liability
- [ ] 196 Franchise

REAL PROPERTY
- [ ] 210 Land Condemnation
- [ ] 220 Foreclosure
- [ ] 230 Rent Lease & Ejectment
- [ ] 240 Torts to Land
- [ ] 245 Tort Product Liability
- [ ] 290 All Other Real Property

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PERSONAL INJURY
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- [ ] 315 Airplane Product Liability
- [ ] 320 Assault, Libel & Slander
- [ ] 330 Federal Employers' Liability
- [ ] 340 Marine
- [ ] 345 Marine Product Liability
- [ ] 350 Motor Vehicle
- [ ] 355 Motor Vehicle Product Liability
- [ ] 360 Other Personal Injury
- [ ] 362 Personal Injury -Medical Malpractice

PERSONAL INJURY
- [ ] 365 Personal Injury – Product Liability
- [ ] 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- [ ] 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
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- [ ] 371 Truth in Lending
- [ ] 380 Other Personal Property Damage
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CIVIL RIGHTS
- [ ] 440 Other Civil Rights
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- [ ] 442 Employment
- [ ] 443 Housing/ Accommodations
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- [ ] 446 Amer. w/Disabilities–Other
- [ ] 448 Education

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HABEAS CORPUS
- [ ] 463 Alien Detainee
- [ ] 510 Motions to Vacate Sentence
- [ ] 530 General
- [ ] 535 Death Penalty

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- [ ] 550 Civil Rights
- [ ] 555 Prison Condition
- [ ] 560 Civil Detainee–Conditions of Confinement

FORFEITURE/PENALTY
- [ ] 625 Drug Related Seizure of Property 21 USC § 881
- [ ] 690 Other

LABOR
- [ ] 710 Fair Labor Standards Act
- [ ] 720 Labor/Management Relations
- [ ] 740 Railway Labor Act
- [ ] 751 Family and Medical Leave Act
- [ ] 790 Other Labor Litigation
- [ ] 791 Employee Retirement Income Security Act

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- [ ] 423 Withdrawal 28 USC § 157

PROPERTY RIGHTS
- [ ] 820 Copyrights
- [ ] 830 Patent
- [ ] 835 Patent–Abbreviated New Drug Application
- [ ] 840 Trademark

SOCIAL SECURITY
- [ ] 861 HIA (1395ff)
- [ ] 862 Black Lung (923)
- [ ] 863 DIWC/DIWW (405(g))
- [ ] 864 SSID Title XVI
- [ ] 865 RSI (405(g))

FEDERAL TAX SUITS
- [ ] 870 Taxes (U.S. Plaintiff or Defendant)
- [ ] 871 IRS–Third Party 26 USC § 7609

OTHER STATUTES
- [ ] 375 False Claims Act
- [ ] 376 Qui Tam (31 USC § 3729(a))
- [ ] 400 State Reapportionment
- [ ] 410 Antitrust
- [ ] 430 Banks and Banking
- [ ] 450 Commerce
- [ ] 460 Deportation
- [ ] 470 Racketeer Influenced & Corrupt Organizations
- [ ] 480 Consumer Credit
- [ ] 490 Cable/Sat TV
- [ ] 850 Securities/Commodities/ Exchange
- [X] 890 Other Statutory Actions
- [ ] 891 Agricultural Acts
- [ ] 893 Environmental Matters
- [ ] 895 Freedom of Information Act
- [ ] 896 Arbitration
- [ ] 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- [ ] 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

[X] 1 Original Proceeding | [ ] 2 Removed from State Court | [ ] 3 Remanded from Appellate Court | [ ] 4 Reinstated or Reopened | [ ] 5 Transferred from Another District *(specify)* | [ ] 6 Multidistrict Litigation–Transfer | [ ] 8 Multidistrict Litigation–Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
21 U.S.C. Section 332(a)

Brief description of cause:
To enjoin and restrain defendants from violating the Federal Food, Drug & Cosmetic Act by causing food to become adulterated.

VII. REQUESTED IN COMPLAINT:

[ ] CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, Fed. R. Civ. P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: [ ] Yes [X] No

VIII. RELATED CASE(S), IF ANY *(See instructions):*

JUDGE DOCKET NUMBER

IX. DIVISIONAL ASSIGNMENT (Civil Local Rule 3-2)

(Place an "X" in One Box Only) [X] **SAN FRANCISCO/OAKLAND** [ ] **SAN JOSE** [ ] **EUREKA-MCKINLEYVILLE**

DATE 11/27/2018 **SIGNATURE OF ATTORNEY OF RECORD** James T. Nelson